

ACD BLOOD-PACK UNITS (PL 146 PLASTIC)- dextrose monohydrate, trisodium citrate dihydrate and anhydrous citric acid solution
Fenwal, Inc.

Instructions for Blood Collection Using CPD or ACD Single Blood-Pack™ Units

Integral Donor Tube (IDT)

Rx only

Use aseptic technique.

Precaution: Do not use unless solution is clear.

1. Identify Blood-Pack unit using appropriate donor identification system. Confirm that all numbered tubing of each Blood-Pack unit contains its own identical segment numbers.
2. Adjust donor scale to desired collection weight.
3. Position primary container from donor scale as far as possible below donor arm and clamp donor tubing with hemostat.
4. Apply pressure to donor's arm and disinfect site of venipuncture.
5. If blood pressure cuff is used, inflate to approximately 60 mmHg.
6. Remove needle cover per instructions below:
 - (a) Holding the hub and cover near the tamper-evident seal, twist cover 1/4 turn to break seal.
 - (b) Remove needle cover, being careful not to drag the cover across the needle point.

Perform venipuncture, appropriately secure donor needle and/or tubing and release hemostat.

7. **Mix blood and anticoagulant at several intervals during collection and immediately after collection.**
8. Collect the appropriate volume based on Blood-Pack unit used. Note: The volume of anticoagulant is sufficient for the blood collection indicated on Blood-Pack unit \pm 10%.
9. Apply hemostat to donor tube.
10. As appropriate, release pressure on the donor's arm, collect donor samples following established procedures and withdraw donor needle.

Precaution: Use care to avoid accidental needle sticks. One of the Fenwal Needle Protector Systems may be used to reduce the risk of needle stick injury.

11. Strip blood from donor tubing into container, mix and allow the tubing to refill; repeat once. Seal at X marks on donor tubing to provide numbered aliquots of anticoagulated blood for typing or crossmatching.
12. Discard needle into an appropriate biohazardous waste container following established procedures.
13. Store filled unit between 1 and 6° C.
14. Infuse blood within 21 days of collection.

Store at Controlled Room Temperature.

USP Definition of "Controlled Room Temperature"

United States Pharmacopeia, General Notices.

United States Pharmacopeial Convention, Inc.

12601 Twinbrook Parkway, Rockville, MD

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Manufacturer

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Fenwal, Inc.

Lake Zurich, IL 60047 USA

1-800-933-6925

Made in USA

07-19-02-335 REV: A 02/2009

PRINCIPAL DISPLAY PANEL

Fenwal™

Anticoagulant Citrate Dextrose Solution, USP (ACD) Formula A BLOOD-PACK™ Unit

Single For Collection of 450 mL Blood

Integral Donor Tube, 16 ga. Ultra Thin Wall Needle

Rx only

Each unit consists of a PL 146 Plastic primary container with 67.5 mL of ACD solution containing 1.65 g Dextrose (monohydrate) USP, 1.48 g Sodium Citrate (dihydrate) USP and 493 mg Citric Acid (anhydrous) USP.

Sterile, non-pyrogenic fluid path

See instructions for use.

Store at Controlled Room Temperature (refer to direction insert).

- Open pouch by tearing across at notch.
- Direct handling of product surfaces prior to extended storage in the foil pouch, may result in mold growth.
- Unused units in open foil pouch may be kept up to 60 days by folding and securing open end of foil pouch to prevent possible loss of moisture, provided:
 - I) Units are not removed from foil pouch, or
 - II) Unused units removed from foil pouch are returned to the foil pouch within 12 hours. Units may be removed from the pouch and returned only once.
- Units removed from the foil pouch (that are not returned to the pouch within 12 hours) must be used within 4 days (96 hours). Units out of the foil pouch for longer than 96 hours must be discarded.

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Fenwal, Inc.

Lake Zurich, IL 60047 USA

Made in USA

07-28-05-456 REV: A



Anticoagulant Citrate Dextrose Solution, USP (ACD) Formula A BLOOD-PACK™ Unit

Single For Collection of 450 mL Blood

Integral Donor Tube, 16 ga. Ultra Thin Wall Needle

Rx only

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Sterile, non-pyrogenic fluid path
See instructions for use.

Store at Controlled Room Temperature (refer to direction insert).

- Open pouch by tearing across at notch.
- Direct handling of product surfaces prior to extended storage in the **foil** pouch, may result in mold growth.
- Unused units in open **foil** pouch may be kept up to 60 days by folding and **securing** open end of **foil** pouch to prevent possible loss of moisture, provided:
 - I) Units are not removed from **foil** pouch, or
 - II) Unused units removed from **foil** pouch are returned to the **foil** pouch within 12 hours. Units may be removed from the pouch and returned only once.
- Units removed from the **foil** pouch (that are not returned to the pouch within 12 hours) must be used within 4 days (96 hours). Units out of the **foil** pouch for longer than 96 hours must be discarded.



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ACD BLOOD-PACK UNITS (PL 146 PLASTIC)

anticoagulant citrate dextrose (acd) solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0942-9001
Route of Administration	INTRAVENOUS	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	1.65 g in 67.5 mL

TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)		TRISODIUM CITRATE DIHYDRATE	1.48 g in 67.5 mL	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)		ANHYDROUS CITRIC ACID	493 mg in 67.5 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0942-9001-01	67.5 mL in 1 BAG		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NDA	BN160918		03/01/2007	

Labeler - Fenwal, Inc. (794519020)

Establishment			
Name	Address	ID/FEI	Business Operations
Fenwal International		091164590	MANUFACTURE(0942-9001)

Revised: 11/2012

Fenwal, Inc.